

ORIGINAL ARTICLE

Safety and efficacy of Trimax-360 serum in healthy adult subjects with mild to moderate alopecia of scalp

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Abstract

Background: Male pattern baldness and female pattern baldness, commonly known as androgenic alopecia, is the most prevalent type of alopecia, often genetically predetermined. It is a condition of hair loss, which typically affects the scalp and characterized by progressive terminal hair loss.

Objectives: The study was conducted to evaluate efficacy and safety of botanical-based Trimax-360 Serum in healthy adult subjects with mild to moderate alopecia of scalp.

Methods: A total of 30 subjects were randomized in an open label, single arm study conducted in healthy males and females aged 30–45 years. Trimax-360 Serum was applied twice a day for 98 days to each subject. Effect of Trimax-360 Serum was evaluated for hair thickness, hair density, scalp condition, hair fall, hair oiliness, softness, and hair growth rate assessment.

Results: Statistically significant [p -value <0.0001] improvement was observed in hair density, hair thickness, and hair growth rate after 98 days treatment with Trimax-360 Serum. The trend of improvement in change from Baseline was gradual from Day 21 to Day 98 which was found to be 1.7%–41.5% for hair density; 0.00 μm to 10.7 μm for hair thickness, respectively. The mean (\pm SD) hair growth rate ($\mu\text{m}/\text{day}$) also gradually improved from 13.044(\pm 9.4119) to 42.528(\pm 18.5565) $\mu\text{m}/\text{day}$ after 21 days to 98 days treatment with Trimax-360 Serum. All subjects showed good scalp condition and gentle increase in noticeable new hairs while none of the patient reported hair oiliness and hair fall. No apparent adverse events were observed throughout treatment duration.

Conclusions: The results of this open label study suggest that 98 days treatment with botanical-based Trimax-360 Serum is safe and effective in significantly improving the rate of hair growth.

KEYWORDS

androgenic alopecia, hair loss, pattern baldness, post-inflammatory hyperpigmentation

1 | INTRODUCTION

Alopecia is a common and distressing clinical condition that is characterized by hair loss from the scalp and other body parts. Diverse categories of alopecia have been classified based on symptoms,

causes and pattern. Androgenic alopecia, Alopecia areata, and chemotherapy-induced alopecia are major types of hair loss.¹ Of these, androgenic alopecia is the most predominant form of alopecia, which is categorized by progressive terminal hair loss. It is a condition of pattern hair loss that typically affects the scalp, often

genetically predetermined rather than a dermatological condition. It affects both men and women population globally. Androgenic alopecia is characterized by progressive terminal hair loss in a particular pattern.² Though hormone metabolism and androgen receptors play vital role in pattern baldness, principally it is considered a polygenic condition that occurs due to an excessive response to androgen.

On the contrary, Alopecia areata often known as spot baldness, is a medical condition, in which hair is lost from the scalp in patches.³ It is sometimes associated with vitiligo and autoimmune thyroid conditions, often spares gray hairs.⁴ It is an autoimmune condition where body's own immune system attacks own body.⁵ Later on, the body attacks its own hair follicles. This form of hair loss is triggered by genetic makeup of an individual, combined with various other factors.^{6,7}

Male pattern baldness is the principle cause of hair loss in males that usually occurs any time after puberty. It usually affects temporal regions, vertex, and mid-frontal scalp. Androgenic alopecia in women is also known as female pattern baldness or hair loss. The incidence is more or less same as in men; however, inheritance pattern differs where, comparatively more hair loss can be observed in frontal and parietal region, while occipital scalp shows lesser hair thinning.⁸ 5-alpha reductase enzyme plays vital role during metabolism of testosterone that produces dihydrotestosterone (DHT). The latter has higher binding affinity as compared with other androgens at the receptor sites and accelerates baldness comparatively faster and considered accountable for the typical reduction of scalp hair follicles in a specific pattern in androgenic alopecia. Thus, lowering the DHT level might play key role in the prevention and treatment of androgenic alopecia patients.⁹

Typical alopecia treatment for adult includes the use of intral-lesional/topical corticosteroids, minoxidil, systemic corticosteroids, immune-suppressants, topical immunotherapy, and inhibitors of Janus kinase. These therapies are usually administered through local injections, topical ointment application, or orally.¹⁰ However, long-term use of corticosteroid treatment can cause serious side effects. The latter includes diabetes, high blood pressure, and bone thinning. It also has a high rate of hair loss recurrence once the treatment is stopped. To minimize hair loss, continued treatment is required. While minoxidil is occasionally applied off-label as monotherapy or as a combination therapy with other treatments, the use of immune-suppressants is limited in children because frequent blood tests are required during the treatment to monitor potential side effects. The disadvantages of topical immunotherapy include high relapse rate especially in the more diffuse types of hair loss, mainly given to the patients with more than 50% scalp involvement, and lesions become more refractory, long-term treatment with side effect such as eczematous reactions, sleep disturbances, severe urticarial reaction, or severe dermatophism.^{11,12}

Therapeutic result from various studies suggests that administering chemical-based and synthetic compounds for alopecia treatment has numerous side effects including itching, acne at application site, erythema, scaling, pruritis, and dermatitis. Natural treatments, however, have comparatively less sideeffects. The later has more acceptance,

patient compliance and multiple mode of action on alopecia. The mechanism of action described for the available natural treatments include nutritional support (minerals, vitamins, and antioxidants), DHT blockers and 5- α - Reductase blockers, aromatherapy, and improvement of blood circulation into the scalp. Vitamin A, B complex, E, Coenzyme Q10 and minerals viz. Calcium, Iron, Zinc and Magnesium are essential elements required for promoting hair growth, healthy scalp, hair follicles, lubrication of hair roots, and retaining healthy sebum in the scalp. Essential oils are the active constituent of different plant parts used in aromatherapy that play vital role in strengthening blood circulation and nervous system stimulation. The role of DHT in hair fall is scientifically well established and the botanicals having these nutritional elements, essential oils, and DHT blocking activity have great potential in hair loss protection and alopecia treatment.¹³

However, the investigational product used in this study is plant based and the ingredients of "Trimax-360 Serum" are botanical in nature including organic Argan oil, Jojoba oil, Grape seed oil, Tocotrienols, and Capric/Caprilic triglycerides. Organic Argan oil is considered rich in natural phenolic compounds that directly benefits hair follicles. Jojoba oil, which is also good for hair care, grape seed oil, and Tocotrienol both are potent antioxidants that protects the hair and preserves hair integrity with no side effects. Hence, the present open label, single arm study was taken up to evaluate the safety and efficacy of Trimax-360 Serum containing natural ingredients in terms of improvement in hair growth rate, density, and thickness along with scalp condition in healthy adult subjects with mild to moderate Alopecia of scalp. The study was also aimed to evaluate the hair characteristic by self-assessment questionnaire and assess scalp dryness, dandruff, hair brightness and beauty, itching, damaged hair by dermatologist.

2 | MATERIALS AND METHODS

2.1 | Study design and participants

A single arm, open label study was designed to evaluate safety and efficacy of Trimax-360 Serum in healthy adult human subjects with mild to moderate alopecia of scalp.

The study consisted of 6 visits that included screening visit (Within 14 days prior to Day 1), enrolment/randomization visit (Day 1), treatment phase and end of the study visit [Day 21, Day 42, Day 70, and Day 98 (± 2 days)]. End of study procedure was performed on Day 98. Instrumental assessment, dermatological assessments, and questionnaires were performed for the evaluation of efficacy. Safety was assessed throughout the study by monitoring of adverse events.

The study duration was 98 days from Day 1, that is, enrolment. Written informed consent was obtained from the subjects, and ethics approval was taken prior to the commencement of the study. The prospective subjects were screened in accordance with the inclusion and exclusion criteria prior to commencement of the study. The test products were provided to the eligible subjects for 98 days (14 weeks) application.

2.2 | Inclusion criteria

Healthy subjects of 30–45 years age group, who had mild to moderate alopecia of scalp (main inclusion for the study) were enrolled in this study. Female subjects of childbearing age group, had to report on the first day of menstruation on enrolment day. Male subjects with Norwood Pattern II to VI of hair loss and female subjects with Ebling and Rook five-stage classification I or II of hair loss; subject willing to refrain from any other treatment for the main indications for which the study drugs are being given during the course of the study; subjects who committed not to use medicated/ prescription shampoos/hair care products (containing Minoxidil / Anti-hair fall agents) or any other hair fall treatment/ hair products other than the test product for the whole study period; subjects willing and able to follow the study directions to participate in the study and subjects willing to allow photographs of affected areas to be taken before and after application of test product, were other key inclusion criteria.

2.3 | Exclusion criteria

Subjects fulfilling any of the listed criteria were excluded from the present study: history of any dermatological condition of the scalp other than hair loss and/or dandruff; history of prior use of scalp hair growth treatment within 3 months; history of any prior hair growth procedures (i.e., hair transplant or laser); subjects who had applied topical treatment for hair loss for at least 4 weeks and any systemic treatment for at least 3 months, prior to their participation in the study; history of alcohol or drug addiction; subjects using other marketed hair fall control products during the study period; subjects who were on chronic oral steroids 03 months before initial application and during the study period; history or present condition of irritated or visibly inflamed scalp or severe scalp disease; subjects having a history of allergic reaction or present condition of allergic response to any cosmetic products or ingredient of study product; any other condition which could warrant exclusion from the study, as per the dermatologist's/investigator's discretion; breastfeeding, pregnant females or planning to become pregnant during the study period; subjects participating in other similar cosmetic or therapeutic trial within last 2 weeks.

2.4 | Study drug

All 30 enrolled subjects received test product as per randomization code. The subjects were asked to apply 4–5 drops of Trimax-360 Serum on affected areas on the head at night. They were allowed to leave the product as it is or may wash the hair next morning. The application area was then evaluated at each visit subsequently to observe the effect of the test product on hair characteristics (Hair thickness, density, scalp condition, hair growth rate, hair fall, oiliness, and softness) by performing the instrumental assessment and self-assessment questionnaire. Safety of Trimax-360 Serum was also

assessed in healthy adult subjects with mild to moderate alopecia of scalp.

2.5 | Efficacy endpoints

The primary efficacy endpoints were evaluation of hair thickness, hair density, scalp condition, and hair growth rate before application of Trimax-360 Serum and after each subsequent application. Secondary efficacy endpoints include subject's self-assessment questionnaire for hair fall, hair oiliness, and softness before application and after each subsequent application.

2.6 | Safety endpoints

Subjects were investigated for adverse events (AEs) at the time of each study facility visit. They were also asked to contact the investigator to report the expected and unusual AEs at any point of time. Furthermore, safety evaluation was performed with the assessment of scalp dryness, dandruff, hair brightness and beauty, itching, and damaged hair by dermatologist.

2.7 | Instrumental measurement

The analysis of the hair growth was done by Vernier Caliper—a measuring device for accurate linear measurements. This instrument consists of three elements, that is, the beam, the sliding jaw, and the fixed jaw. It precisely measures linear dimensions of an object. Vernier Caliper (Make: HI-Mezar) was used as mentioned in operating instruction manual. Hair thickness, density, growth rate, and scalp condition were measured by CASlite Nova (Make: CATS EYE system & solution).

2.8 | Statistical analysis

Statistical analysis of the recorded data was performed by SAS[®] statistical software (Version: 9.4; SAS Institute Inc.). Continuous variables were described by descriptive statistics (i.e. Mean, Median, Min, Max). Frequency and percentage of each category were calculated for categorical variables. All statistical tests of hypothesis were done at 0.05 level of significance.

2.9 | Ethics

The authors confirm that all the ethical policies mentioned in the author's guidelines page of the journal have been adhered to. Appropriate approval on Study Protocol (KLS18-MAX-226 dated April 10, 2019) and informed consent document (ICD) had been received from ethical review committee prior to commencement of

trials. The study was explained to all prospective subjects, and ICDs were signed before commencement of the clinical study. Description of the test product being evaluated was explained by the investigator including potential hazards, allergies, and possible anticipated reactions.

The clinical study was carried out in accordance with The International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH)-GCP (E6 R2) and applicable ethical guidelines.

3 | RESULTS

3.1 | Subject disposition and demography

Experimental studies generally need lesser sample size as compared with observational studies. Looking to the various limitations, sample size calculation was done based on past experience of similar study in consultation with medical monitor. The investigator preferred to choose small and feasible sample size for this study rather than picking an arbitrary sample size. Study design was thus chosen single arm to ensure that adequate test subjects are available for statistical analysis and interpretation. In the present study, total of 53 subjects were screened, out of which 30 subjects with mean (\pm SD) age of 38.9 (\pm 4.18) years were randomized and enrolled, fulfilling inclusion criteria. Out of total enrolled ($n = 30$) subjects, four subjects were excluded from the study including three subjects who did not appear for follow-up visits; and one subject withdrew himself later on. Total 26 subjects (06 Females, 20 Males) completed all six visits as per proposed study design and data were successfully recorded. (Table 1).

3.2 | Efficacy assessments

Under efficacy assessment, the primary outcome of the study was to assess efficacy of Trimax-360 Serum on hair thickness, hair density, hair growth rate, and scalp condition that was measured by CASLite Nova Phototrichogram and Vernier Caliper before application to after application. The secondary efficacy outcome was to evaluate the product performance in reduction of hair fall, hair oiliness, and softness before application to after application of Trimax-360 Serum.

TABLE 1 Summary of demographic characteristics

	Treatment group
Age (years)	
N	30
Mean \pm SD	38.9 (\pm 4.18)
Median	39.0
Min, Max.	31, 45

Note: N, number of subjects.

TABLE 2 Summary of %CFB for hair thickness, hair density, hair growth rate at each treatment visit

Treatment day	Hair thickness (%)	Hair density (%)	Hair growth rate (%)
Day 21	0.00	1.05	147.73
Day 42	20.81	12.36	682.00
Day 70	43.93	18.70	1463.68
Day 98	61.85	25.52	2324.86

3.3 | Primary efficacy parameters

3.3.1 | Increase in hair thickness, hair density & scalp condition

Efficacy of Trimax-360 Serum was measured in terms of hair thickness, density, and scalp condition by CASLite Nova Phototrichogram before (Day 1) and after application (Day 21, Day 42, Day 70, and Day 98). The observation is presented in Table 2 and Figure 1. Treatment with the test product resulted in significant improvement in hair thickness, hair density, and hair growth rate ($p < 0.05$) and almost all patients showed good scalp condition. The improvement was consistent and sustained throughout the treatment period application (Day 21, Day 42, Day 70, and Day 98). The results indicate that application of Trimax-360 Serum for 98 days result in sustained improvement in hair characteristics and hair growth rate.

3.4 | Secondary efficacy parameters

3.4.1 | Subject self-assessment

Efficacy of product performance in reduction of hair fall, hair oiliness, and softness before application to after application of Trimax-360 Serum (Day 1 before application and Day 21, Day 42, Day 70, and Day 98 after application) is represented in Figure 2. 100% subjects showed improvement in dryness of hairs, oiliness of hairs, softness of hairs from poor, average to good.

In self-assessment questionnaire, 100% subjects were in agreement that after use of test product their bald spot getting smaller in size, growth of hairs gently increased, and gentle increase in amount of noticeable new hair while 88.46% and 11.54% subjects responded well and lot better appearance of hair, respectively, as shown in the Figure 3.

3.4.2 | Safety assessment

In safety assessment, 96.15% and 92.31% subjects reported absence of scalp dryness and dandruff, respectively, at the completion of study, while 100% subjects agreed upon the absence of itching and

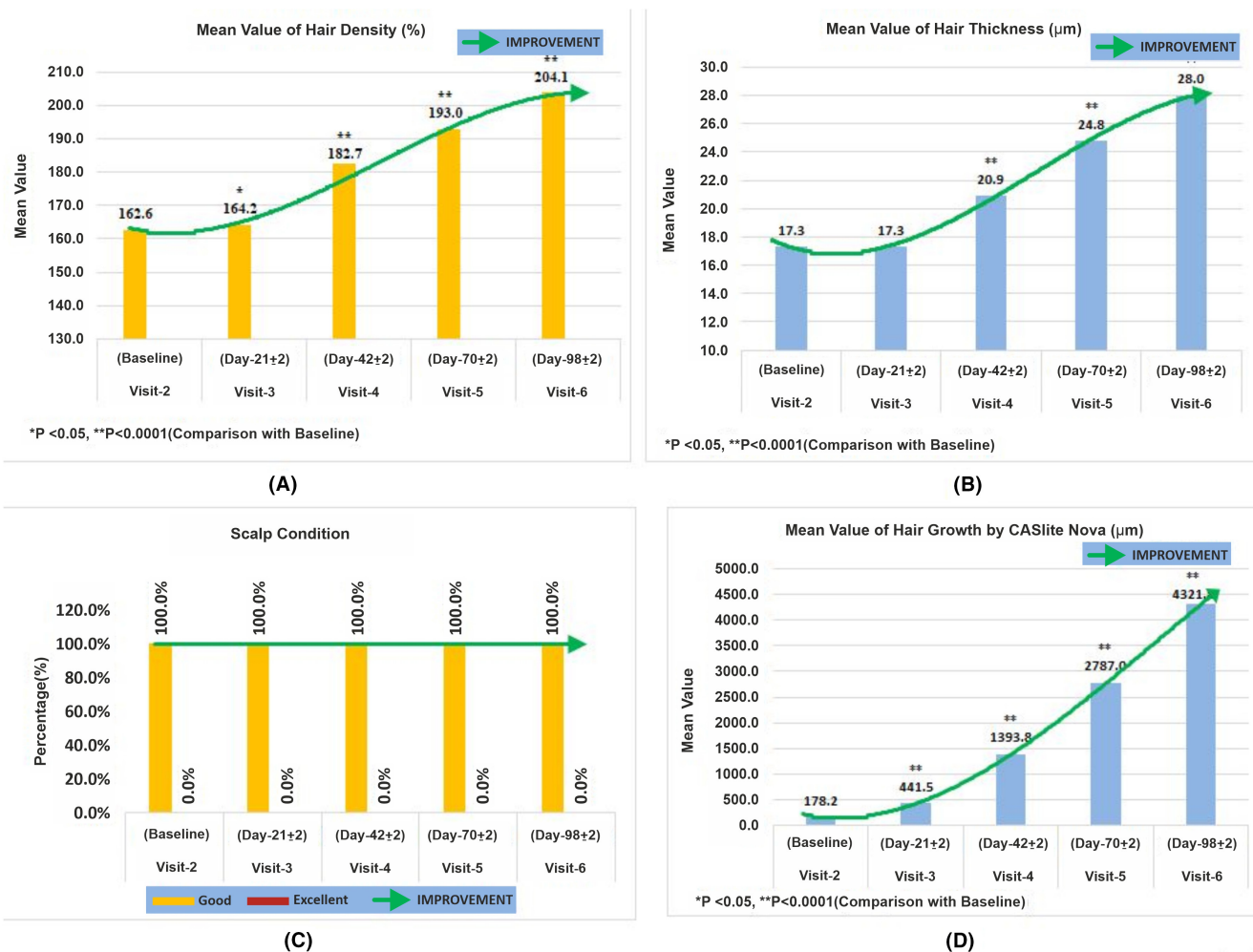


FIGURE 1 Summary of analysis of hair thickness, hair density, hair growth rate, and scalp condition after treatment with Trimax-360 Serum. A—Analysis of the Mean Value of Hair Density (%); B—Analysis of the Mean Value of Hair Thickness (%); C—Percent Scalp Condition; D—Hair Growth (µm) measured by CASLite Nova

damaged hairs after the application of the test product as shown in Figure 4, and no apparent adverse events were observed. Moreover, the trial subjects were satisfied with the improvement shown after application of Trimax-360 Serum.

4 | DISCUSSION

Treatment by botanical and natural ingredients is becoming more popular these days. The present study was aimed to establish safety and efficacy facts of the test product. The results obtained during the study indicates that the Trimax-360 Serum containing natural ingredients viz. organic Argan oil, Jojoba oil, Grape seed oil, Tocotrienols, and Capric/Caprylic triglycerides is significantly effective in improving the hair growth rate along with hair density and hair thickness and helps in maintaining good scalp condition.

Various studies on Argan oil suggests that it gives moisturizing effect to the dry scalp to fight against dandruff. Its Vitamin E content has direct benefits in promoting hair growth and hair

become stronger and healthier. The other phytoconstituents of Argan oil works synergistically for the wellbeing of hair, scalp, and hair follicles. It is also considered a rich source of natural phenolic compounds that gives direct advantage to the hair follicles. Its powerful antioxidants and nourishing fatty acids prevent hair breakage and protects hair loss caused by free radicals hence result in breakage and shedding protection. Dandruff is a skin condition of scalp, which is characterized by excessive scaling, flaking, itching, and inflamed, often pruritic skin. Recurrent and chronic dandruff may resultant to excessive hair shedding and diffuse alopecia in extreme condition.¹⁴ Argan oil is a potential natural ingredient that may help healing scalp plagued by dandruff, itching, and irritation. It may promote new hair growth, thick, healthy, and shining hairs.¹⁵

Another natural ingredient of the investigational product is Jojoba oil that works as a solubilizing agent for airborne particulates usually deposited on the hair surface. It also helps in removing sticky substances that are deposited on hair by using cosmetic preparations. It acts like a natural barrier for moisture by forming

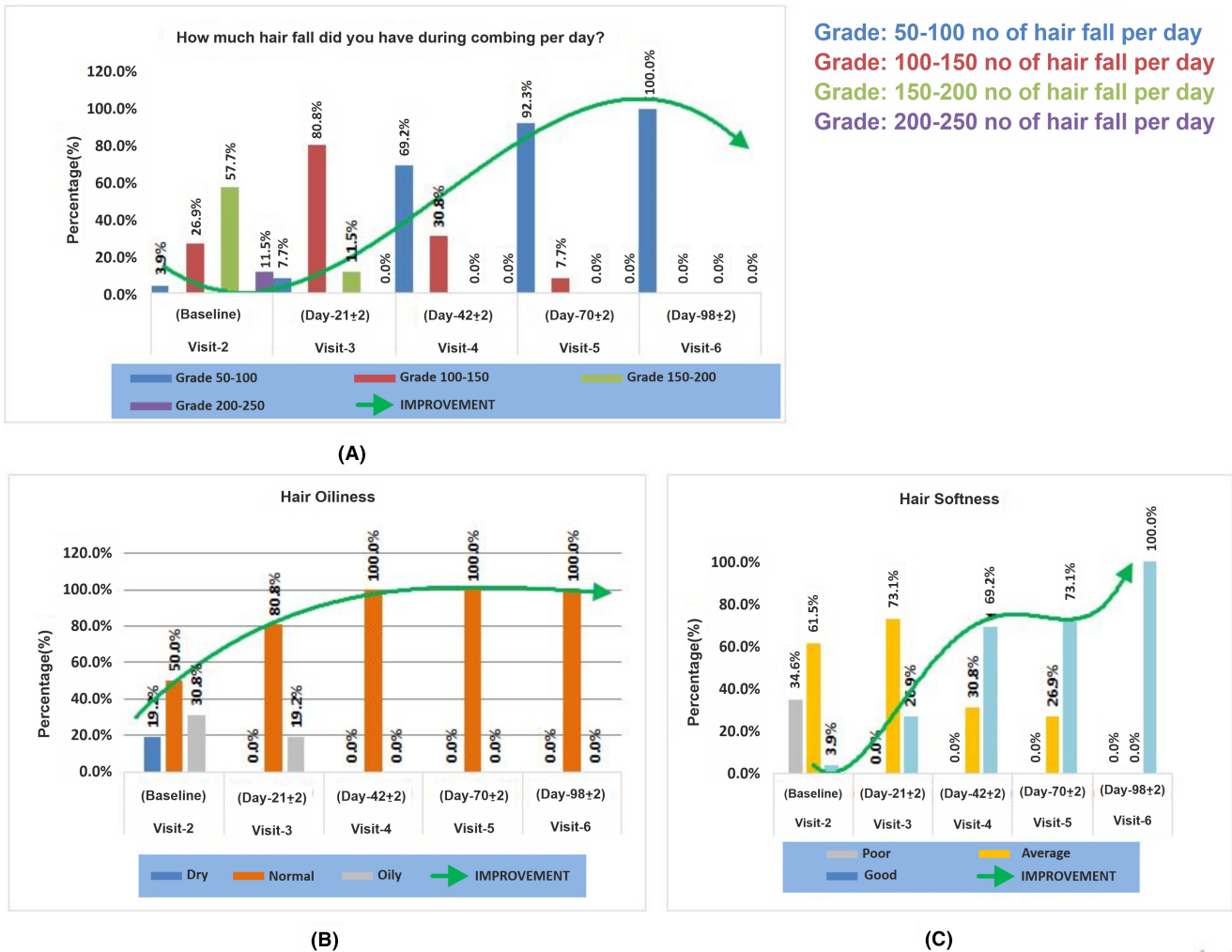


FIGURE 2 Summary of subject's self-assessment in reduction in hair fall, hair oiliness, and softness after application of Trimax-360 Serum. A—Hair fall per day, B—Hair Oiliness, C—Hair softness

a lipid layer on the scalp and prevents from dryness. It penetrates the outermost layer of skin and performs similar action like moisturizing agent. It is a proven and popular agent of various cosmetic and hair care formulations, that is, soaps, shampoos, bath oils, sunscreen lotions, conditioners, moisturizers, creams, and cleansing agents. Jojoba oil gives conditioning effects to the roots of hairs and prevents them from being stiff and dull. It removes sebum deposit by dissolving the later leaving the hair surface clean. Evidence from earlier studies prove that it promotes healthy hair and scalp when applied directly to the roots of hairs.¹⁶ Grape Seed Oil and Tocotrienol both are potent antioxidants that protect the hair and preserve hair integrity with no side effect.¹⁷ The therapeutic benefits of test product containing above discussed natural ingredients have proven efficacy as also evidenced by the results obtained in the present study in human volunteers.

Androgenic alopecia is the most predominant form of alopecia, typically categorized by progressive terminal hair loss in a specific pattern in men and women population. Pattern baldness impacts severely on social and emotional stigma of the affected person.¹⁸

It adversely effects on psychological condition and enhances anxiety and depression henceforth timely treatment of Alopecia is inevitable. Traditional and alternative healthcare system has many potential herbal therapies available for treatment of the condition. It is estimated that there are more than a thousand botanical ingredients that have been studied for the potential hair care benefits. Some natural ingredients, that is, Rosemary oil, Grape seed extract, Hibiscus flowers, Sage, and Nettles help in increasing blood flow and protects from hair fall. On the contrary, Green tea extract, Ginkgo and Emu oil have different mode of action. They inhibit 5-alpha reductase thus lowering dihydro-testosterone. It establishes these ingredients as a potential natural cure for alopecia.¹⁹

In the present study, Trimax-360 hair serum was clinically evaluated for the potential benefits in androgenic alopecia. The test product consisted of botanical ingredients that have been studied earlier and efficacy has been established by several research studies. The different ingredients of the formulation have different mechanism of action and the synergistic effect of these ingredients has

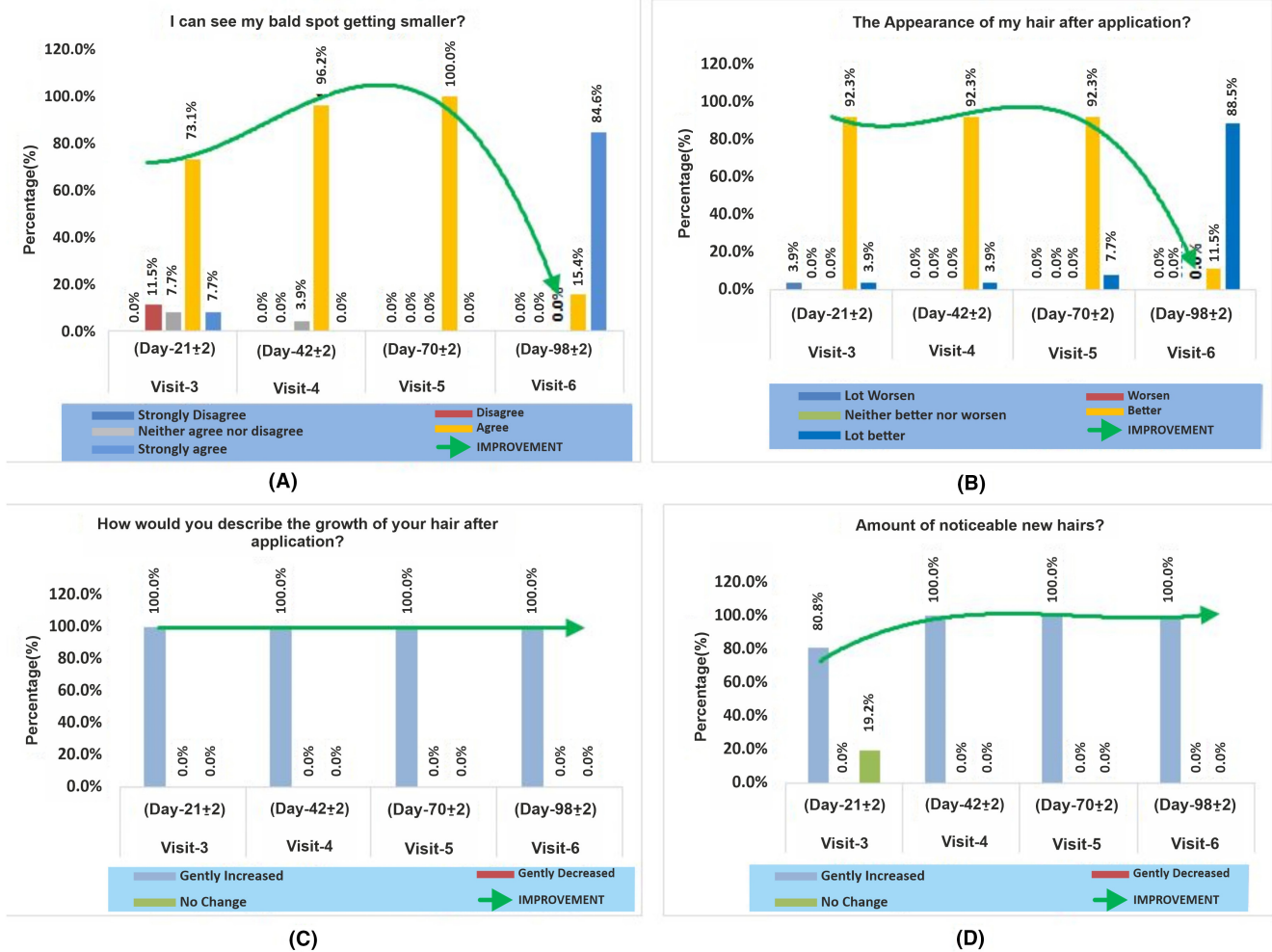


FIGURE 3 Summary of self-assessment questionnaire. A—Bald spot getting smaller in size, B—Appearance of my hair after application, C—Growth of your hair after application, D—Amount of noticeable new hairs

been established for reduction in hair fall, hair growth promotion, and a potential alternative for alopecia treatment. The present study was designed for 98 days treatment with Trimax-360 serum. Results were promising, and it showed significant improvement in maintaining good scalp condition, along with hair growth rate, hair density, and hair thickness. Almost, similar results were observed in open label study conducted in healthy adult volunteers (male and female inclusive) with self-perceived hair fall where highly significant improvement was observed in hair density, hair growth rate, and significant reduction in hair fall (<0.0001) after application of hair serum.²⁰

There are many studies using botanical ingredients to treat hair loss. A review of literature on previous studies confirms that botanical ingredients, combined in a synergistic way, can be very effective for treating alopecia. In a placebo-controlled, randomized study conducted among healthy male population suffering from grade II to IV alopecia, promising results were obtained by treatment of human follicle stem cell in hair growth promotion and modulating the activity of hair follicle.²¹ In a randomized, single-blinded, vehicle-controlled study carried out among the women subjects having androgenic alopecia,

new topical botanical lotion was applied. The treatment had shown noteworthy effects along with improved quality of life and patient satisfaction.²² Another 6-month open label prospective clinical study conducted in patients with androgenic alopecia, hair loss lotion containing different cosmetic ingredients was applied for 6–12 months. The outcome reported that once-daily use of the test product was found effective and safe treatment for topical hair loss. The results demonstrated that total and anagen hairs, overall thickness, and scalp coverage was significantly improved and subjects were agreed upon reduced hair fall.²³

In the present study, almost all subjects showed improvement in dryness of hairs, oiliness of hairs, softness of hairs from poor, and average to good. Moreover, 100% subjects agreed that after use of test product their bald spot getting smaller in size, growth of hairs gently increased, and gentle increase in amount of noticeable new hair while 88.46% and 11.54% subjects responded better and lot better appearance of hair. After 42 days application of Trimax-360 Serum, hair on alopecia site grown very well, and this was noticeably visible to the eye. In general condition, hair density and hair thickness decreases in patients with mild to moderate alopecia. However,

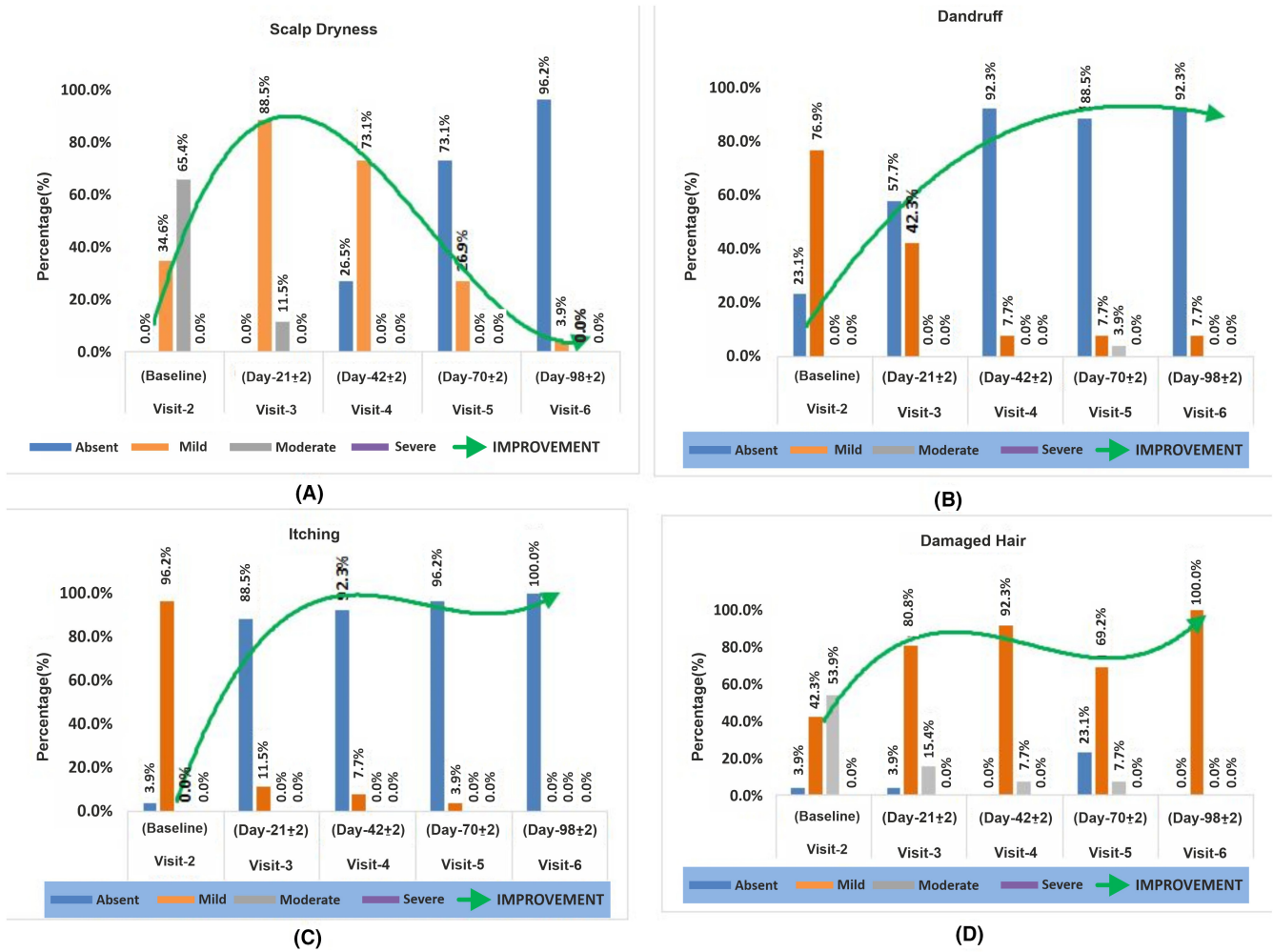


FIGURE 4 Summary of safety parameters after application of Trimax-360 Serum. A—Scalp Dryness, B—Dandruff, C—Itching, D—Damaged hairs

after continuous use of Trimax-360 Serum for 98 days, the hair density and thickness significantly improved.

Rate of hair growth ranges between 2 and 10 mm per month depending on duration of disease and product used for treatment. According to the data, various individual oral and topical preparations for alopecia have given result varying from 30% to 60%.

Hair growth rate measured by Vernier Calliper showed increased hair growth by 3.94 cm/month [normal hair growth rate is 1.25 cm/month in healthy humans],²⁴ in subjects with mild to moderate Alopecia which is generally observed in healthy human as a normal hair growth; so, it can be concluded that Trimax-360 Serum helps in improvement of hair growth rate after usage of 98 days. All the subjects expressed satisfaction and agreed upon the ease of application during the study duration.

In safety assessment, 96.15% and 92.31% subjects reported absence of scalp dryness and dandruff, respectively, at the end of study while 100% subjects reported absence of itching and damaged hairs with apparent adverse events after the application of Trimax-360 Serum.

5 | CONCLUSION

In the present open label study, botanical-based Trimax-360 Serum was evaluated for its safety and efficacy. The test product has shown significant improvement in hair growth, rate along with hair density, and hair thickness. It was found to be effective and safe with no adverse events. Moreover, it has the added benefit in reducing dandruff. Hair growth rate measured by Vernier Calliper showed increase by 3.94 cm/month [normal hair growth rate is 1.25 cm/month in healthy humans]. In this study, mild to moderate androgenic alopecia subjects showed normal hair growth as like healthy human, which indicates that the test product helps in improvement of hair growth rate which was significant as early as 42 days and even much more after 98 days of treatment with twice daily applications. Application of Trimax-360 serum also results in reduction of dandruff, a condition which has been often linked to alopecia. This ability to reduce dandruff is a useful synergistic benefit for using Trimax-360 over other hair loss treatments that do not have this attribute.

Thus, it can be concluded from the present study that synergistic effect of botanical-based ingredients of Trimax-360 is effective in treating hair loss as evidenced by the results of trial parameters. Its regular application twice in a day on the scalp significantly improves hair growth rate along with hair density and hair thickness. It also helps in maintaining good scalp condition, and statistically significant reduction was observed in hair fall reduction. Furthermore, no apparent adverse event was reported during the study, thus, proven a potent treatment for the management of mild to moderate alopecia of the scalp in male and female population.

5.1 | Limitation

This study was limited by study design, non-comparative, and small sample size as it was open label, included no comparison with an active control regimen.

CONFLICT OF INTEREST

The authors are agreed with the content of this manuscript, and they have no conflict of interest to declare. It is also declared that the submission is original and not submitted elsewhere for publication.

ETHICAL APPROVAL

The authors confirm that all the ethical policies have been adhered to and appropriate approval had been received from ethical review committee prior to commencement of trials.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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